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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,415	06/22/2006	Arjan van der Plaats	39612	3606

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EXAMINER	
HENKEL, DANIELLE B	
ART UNIT	PAPER NUMBER
4112	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,415	PLAATS ET AL.	
	Examiner	Art Unit	
	DANIELLE HENKEL	4112	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This is the initial Office action on the 10/566415 application filed on June 6, 2006.

2. Claims 1-9 are pending and have been fully considered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the handgrips or carrying handles of claim 9 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

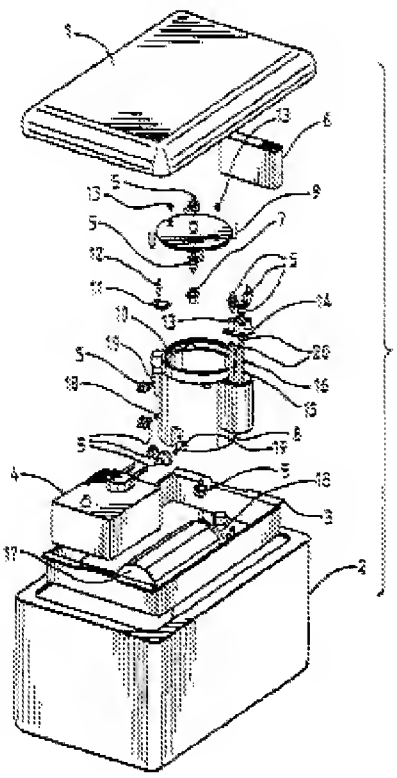
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over ALFORD (US 2003/0054540) and further in view of MESSIER (US 5681740).

a. With respect to claim 1, ALFORD discloses an organ preservation apparatus comprising a cooler (2, Paragraph 0039) with an organ container (8, Paragraph 0037), a lid (1), a perfusion fluid pump with a capacity of 8-10 mL/min/100 grams of organ (miniature pump) (24, Paragraph 0053), a compressed oxygen canister (17, Paragraph 0037), an oxygenator (21, Paragraph 0037), and a battery (31, Paragraph 0053) with an AC-DC transformer (33, Paragraph 0053) (power supply) (See Figure 2).

FIG. 2



ALFORD teaches the perfusion fluid pump has a capacity of 8-10 mL/min/100 grams of organ (miniature pump) and is mounted on the top of the pump assembly box with an easily accessible on-off switch (Paragraph 0053). It would be an obvious design variation to mount the pump partially in the lid of the claimed invention to maintain the accessibility of the switch. ALFORD also teaches the use of a pulse width modulator (electronic module) for control of the perfusion rate (Paragraph 0064). The apparatus of ALFORD also includes an adaptor or standpipe (7) (connecting piece) located on the underside of the organ container cover that the aorta of a human heart is connected to (connected with donor organ) (Paragraph 0047). ALFORD teaches that the adapter (7) is connected to tube B (pipe) that carries perfusion fluid from the pump (connected

with perfusion pump) through an oxygenator and bubble chamber to the organ (Paragraphs 0058-0060). ALFORD does not explicitly disclose a connector detachably connected to the lid on the side facing the organ chamber. However, MESSIER teaches a bioartificial organ storage and transport container that includes a cap (12) (connector) on a media storage container (10) (organ chamber) (Figure 1, Column 8, lines 4-8).

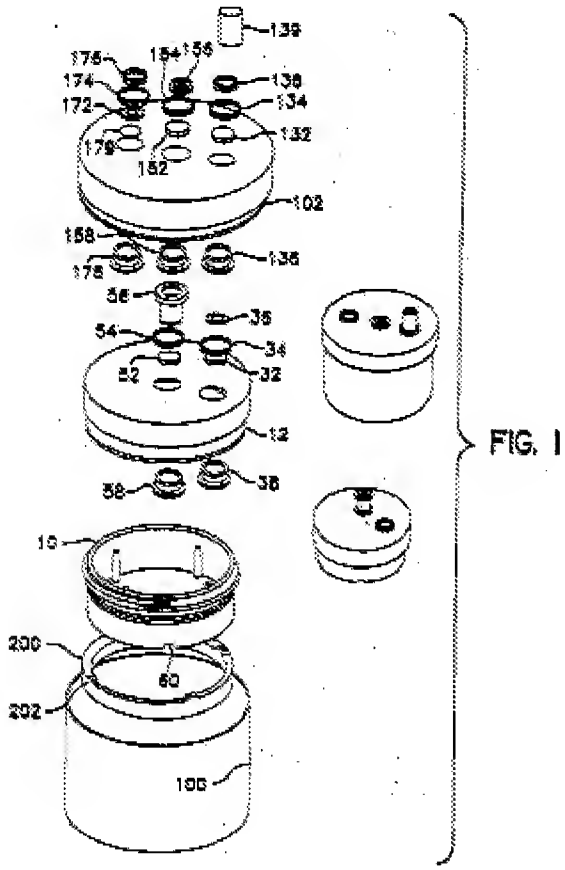


FIG. 1

The cap (connector) has ports for gas exchange (50) and media exchange (30) (passages) (Column 7, lines 16-18). MESSIER teaches the connector (12) is connected to a lid (102) through the gas accessing means (150) of the lid with self-sealing septa in snap fit housing in which a needle is inserted through the

connector to the organ chamber (detachably connected) (Column 8, lines 19-27). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the organ preservation container of ALFORD to include the connector of MESSIER so that the lid is detachable. The motivation would have been that MESSIER teaches that having the organ chamber with the connector portion detachable from the lid allows for the organ chamber to be removed outside the sterile field and only the chamber delivered into the sterile field (Column 9, lines 63-66). MESSIER teaches this reduces the potential of introducing unwanted biological contaminants into the sterile field (Column 9, lines 66-67).

b. With respect to claim 8, MESSIER teaches the cap (12) (connector) is a threaded lid (circumferential grooves) to mate with threads on the top of the media storage container (10) (organ container).

6. Claims 2, 3, 4, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over ALFORD (US 2003/0054540) in view of MESSIER (US 5681740) as applied to claims 1 and 8, and further in view of BACCHI (US 5285657).

a. The combination of ALFORD and MESSIER teaches the portable preservation apparatus of the present application wherein said apparatus comprises a detachable connector. With respect to claim 2, BACCHI teaches an organ transporting vessel (organ chamber) with a lid (connector) having multiple partitions which are parallel providing a chamber (open on one side) similar to having a double bottom (closed wall facing organ chamber) (Column 7, lines 10-

15). The partitions have a central passage for a flexible sleeve to receive a pipe and connectors for sensors which measure conditions inside the vessel (Column 7, lines 24-40). It would be a simple design variation to omit the top partition of BACCHI to form a connector with an open side facing the lid. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the organ preservation container of ALFORD and MESSIER to include the connector of BACCHI. The motivation would have been that BACCHI teaches the chamber formed in the lid allows for access and the maintenance of asepsis of the sleeve providing contact with the interior of the container (Column 7, lines 13-29).

b. With respect to claim 3, BACCHI teaches an organ transporting vessel (organ chamber) in which the body and lid are separated and independently packaged (Column 7, lines 42-44). BACCHI also teaches the dish portion of the double-bottom lid houses (mounted in connector) catheters, probes, cannule, and sensors (fluid pipes) (Column 7, lines 50-53). BACCHI also discloses that this transporting vessel is of the disposable and single-use type (Column 8, lines 18-22). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the organ preservation container of ALFORD and MESSIER to include the single-use transporting vessel of BACCHI. The motivation would have been that BACCHI teaches that separate packing of the lid and vessel allows for each to form autonomous aseptic entity (Column 7, lines 44-45). BACCHI also teaches the conditions of asepsis may be strictly observed

as the constituents are only used once and therefore do not have to cleaned and sterilized (Column 8, lines 22-28).

c. With respect to claim 4, BACCHI teaches a pumping unit of a motor and pump head (detachable driving motor) in which the motor is mounted in an outside service compartment with the pump head inside the main enclosure with the organ transporting vessel (Column 4, lines 17- 35). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the organ preservation container of ALFORD and MESSIER to include the pumping unit of BACCHI. The motivation would have been that BACCHI teaches the container of this design makes it possible to improve the quality and duration of organ preservation while being reliable, easy to use, secure, and of universal use (Column 9, lines 14-18).

d. With respect to claim 6, BACCHI teaches a control unit with sensor-actuators especially for controlling the connected pumping unit (Column 4, lines 35-46) and a display screen (Figure 4, #42). BACCHI also teaches the software management centre of the control unit is installed on a personal microcomputer (Column 4, lines 59-61). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the organ preservation container of ALFORD and MESSIER to include the control unit of BACCHI. The motivation would have been that BACCHI teaches the control unit allows for the monitoring and recording of data from a variety of factors affecting the organ, such as time elapsed, temperature, flow rate, and pressure (Column 8, 55-68). This allows for

the conditions and progress of the transport to be precisely known at any moment so as to facilitate diagnosis of the received organ (Column 2, lines 39-46).

e. With respect to claim 9, BACCHI teaches the controlled environment medical container with transporting handles (Column 3, line 52). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the organ preservation container of ALFORD and MESSIER to include the transporting handles of BACCHI. The motivation would have been that BACCHI teaches it is important to have a container which allows a preserved organ to be preserved and transported (Column 2, lines 19-22) and the transporting handles allow for ease of transport.

7. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over ALFORD (US 2003/0054540) in view of MESSIER (US 5681740) as applied to claims 1 and 8, and further in view of OWEN (US 6673594).

a. The combination of ALFORD and MESSIER teaches the portable preservation apparatus of the present application wherein said apparatus comprises a detachable connector. With respect to claim 5, OWEN teaches a transporter for an organ which has a control panel which displays characteristics of the transporter (electronic module) located on external surface (Figure 19, Column 12, lines 51-65). It would be a simple design variation to place this electronic module on the lid of the organ preservation container stated in the above combination of ALFORD and MESSIER as this would allow the electronics

to connect directly with the pump, oxygenator, and sensors in the organ chamber via the passages in the connector.

b. With respect to claim 7, MESSIER discloses it is preferable that some components of the storage and transport apparatus be optically clear to allow viewing of the organ (Column 10, lines 45-49). OWEN teaches an organ perfusion apparatus in which an embodiment of the organ container has an inner and outer lid (cover) (Column 10, lines 41-42) that are constructed of an optically clear material (window) to allow for viewing the interior of the cassette (organ chamber) (Column 10, lines 59-60). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the organ preservation container of ALFORD and MESSIER to include the cover with a window of OWEN. The motivation would have been that OWEN teaches the clear lid allows for viewing the interior of the cassette to monitor the organ and allow for images to be taken of the organ to record the progress and status of the organ (Column 10, lines 60-63). The optically clear lid can function as a window for a display screen as it allows for viewing of objects inside the container, which for the current invention would include the display screen.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. FAHY (US 5586438) teaches a device for storage and transportation of an organ with a perfusion pump that is controlled by a microprocessor.

b. GARDETTO (US 5965433) teaches a portable perfusion and oxygenation apparatus that is contained in an insulated chest.

c. HASSANEIN (US 6046046) teaches a device for maintaining an organ for transplantation with a preservation chamber that is provided with an oxygenation perfusion circuit.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE HENKEL whose telephone number is (571)270-5505. The examiner can normally be reached on Mon-Thur: 7:30am-5pm, Alternate Fridays: 7:30am-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara Gilliam can be reached on 571-272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBH

/Barbara L. Gilliam/
Supervisory Patent Examiner, Art Unit 4128